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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,380	02/08/2002	Li-Lan H. Chen	366325-503	1761

25561 7590 10/29/2004

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EXAMINER

SPEAR, JAMES M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,380

Applicant(s)

CHEN ET AL.

Examiner

James M Spear

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The response filed 26 March 2004 has been entered.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-5 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zyck et al US 6,541,048 B2. The claims remain rejected for the reasons set forth in the prior office action mailed 24 September 2003.
3. Applicant's arguments filed 26 March 2004 have been fully considered but they are not persuasive. Applicants feel the Zyck et al reference does not teach or suggest a complex of a pharmaceutically acceptable carrier, an active agent and glycyrrhizin, wherein the active agent contains at least one nitrogen-containing moiety and wherein the composition is substantially free of uncomplexed active agent. Applicants further state that Zyck et al does not teach forming a complex by first dissolving glycyrrhizin with an aqueous solvent and then gradually adding the active ingredient to the solution. How a composition is made is not a basis for determining patentability of composition claims. However Zyck et al is considered to teach an admixture just as applicants' composition. Applicants' claim 1 shows a mixture of glycyrrhizin and famotidine in an aqueous solution wherein the aqueous component is removed by drying forming a powder. Table 3 of Zyck et al shows a mixture comprised of an acid blocker preblended with powdered sugar, powdered dextrose, or powder gum arabic that is further dispersed in a coating syrup. The reference further teaches incorporation of water by wet granulation and spray drying. Column 7, lines 47-60. A coating syrup that is further dried comprised of famotidine and glycyrrhizin would clearly read on applicants' claims.

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See column 9, line 65 through column 10, line 11, column 15, lines 16-21, claims 1 and 3.

4. Claims 1-5 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. The claims remain rejected for the reasons set forth in the prior office action cited above.

5. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the formation of a complex in a process of making) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicants' claims are directed to a product and how the product is made is not a basis for determining patentability. Examples 10 and 11 show a composition comprised of famotidine. It is the position of this office that it would have been obvious to one of ordinary skill in the art to modify the composition by adding the obvious variant glycyrrhizin in place of aspartame. The motivation being a desire to tailor the sweetening properties to an individual's preference because it is well known that the different sweeteners impart different tastes to different individuals. Absent the showing of unexpected results supported by scientific and/or clinical data it is the position of this office that there is no patentable distinction between the prior art and applicants' composition. If applicants form a complex then the prior art does also because the composition components are the same.

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6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink that reads "James M. Spear". The signature is written in a cursive style with a large, sweeping "S" at the end.

James M Spear
Primary Examiner
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October 26, 2004